

Remarks/Arguments

Claims 1-81 are pending. Claims 16-18, 20, 29-38, 40-48, 50 and 60-72 have been withdrawn from consideration by the Examiner due to restriction/election.

The Examiner has rejected claims 1-15, 19, 21-28, 39, 49, 51-59, and 73-81 under 35 U.S.C. § 112, first paragraph, because the specification is deemed non-enabling for the elected species of claim 73. Applicants respectfully disagree and traverse.

The invention is enabled if the specification teaches one of ordinary skill in the art how to make and use the invention without undue experimentation.

Applicants note that the elected compound of claim 73 is the compound of Example 57 (specification page 308), which Example teaches how to make this compound. The specification contains examples demonstrating that this compound may be used as claimed in claim 73, for example, on pages 126 to 137; in particular, data for the elected compound is shown in Table 11 on page 127 and in Table 12 on page 131. Furthermore, even if the specification did not contain examples specifically showing the use of the elected species, the description would still be sufficient to teach one of ordinary skill in the art how to practice the invention. The law does not require that the specification contain specific clinical data.

The Examiner has correctly noted that the level of skill in the art is very high. From Applicants' teaching of the compound, a method for making it and a method of using it, a person of ordinary skill in the art would have no difficulty practicing the invention; any experimentation required to test the elected compound's effects on a particular cancer in a particular case would be routine to those of ordinary skill in this art, and not undue experimentation. Merely because this experimentation could be complex does not make it undue, since those skilled in the art typically engage in such experimentation.

Applicants believe that the description and examples contained in the specification provide ample information to enable one of ordinary skill in the art to practice the claimed invention. The law does not require that Applicants provide examples for every possible use or embodiment of the invention. The burden is on the Examiner to provide reasons, supported by evidence, that the invention is not enabled, and the Examiner has failed to carry this burden.

For the foregoing reasons, Applicants respectfully request withdrawal of this rejection under § 112, first paragraph.

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement in that, “The terms ‘inhibiting’ and ‘eradicating’ are not defined by the claim in any requisite degree. Furthermore, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” (Page 5, last two sentences, of the 4/11/2007 Office Action.) And further, that, “due to the multiplicity of susceptibilities, properties, resistance factors, etc. of any and all cancerous disease states/conditions, the terms ‘inhibiting’ and ‘eradication’ have no factual basis either disclosed in the specification or instant claims. There is no definite degree described either in the instant claims or specification that suggests that the invention is enabled for inhibiting and/or eradicating.” (Page 6, second and third sentences, of the 4/11/2007 Office Action.) Applicants traverse this rejection for the reasons set forth below.

Applicants do not know what the Examiner considers a “requisite degree”; this term is vague, undefined, and not found in 35 U.S.C. § 112, first paragraph.

Claim 1 is directed to a “method for treating, inhibiting the growth of or eradicating a tumor in a mammal....” The Examiner has implicitly conceded that the method of treating is enabled, but has rejected the claim as non-enabling with respect to inhibiting the growth of or eradicating a tumor. An invention is enabled if the specification teaches one skilled in the art how to make and use the invention without undue experimentation. The burden is on the Examiner to provide reasons, supported by evidence, why the Examiner believes that the invention cannot be made or used without undue experimentation.

The level of ordinary skill in the art is very high. Those of ordinary skill understand that the treatment of a tumor may have different results in different cases, for example: stopping tumor growth, slowing tumor growth, shrinking the tumor, or completely eliminating the tumor. They also understand that eradicating means totally eliminating, and inhibiting growth means that the tumor grows less than it would have without treatment. “Inhibiting” and “eradicating” are standard terms in the art, as well as in common English. Those skilled in the art would also understand that when one treats a tumor with a drug it is expected and desired that the drug will inhibit tumor growth, and preferably eradicate the tumor.

The experimental evidence provided in the specification on pages 103-137 support the claimed use. Additionally, the specification states that the present invention provides a method of treating, inhibiting the growth of, or eradicating a tumor in a mammal as claimed (for example, beginning at page 5, lines 12 et. seq.). The Examiner has not provided any evidence that the specification is incorrect in this regard. Although the practitioner may have to do some routine testing to determine how the invention best may be applied in a particular case, including adjusting the dosage for optimal effect, no undue experimentation is needed. The person of ordinary skill in this art routinely makes such determinations.

The teaching of the present invention is that tumors resistant to a chemotherapeutic agent may be treated, inhibited or eradicated by the claimed method. The specification describes how to make the claimed compound(s), and provides examples which demonstrate the efficacy of the compound(s) against resistant cells, and which exemplify compositions and methods of administration of the claimed compound(s). These teachings are sufficient to enable one of ordinary skill in the art to make and use the invention without undue experimentation.

For all the foregoing reasons, Applicants believe that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, is erroneous and respectfully request its withdrawal.

The Examiner has made the restriction/election requirements final. Applicants respectfully request reconsideration thereof.

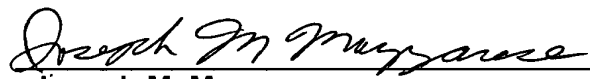
The Examiner must cite reasons to support a restriction requirement. Restriction is not proper unless there would be a serious burden on the Examiner if restriction is not required. It is difficult to see how it could be a serious burden to examine all the claims together when they are all classified in the same class and subclass, and only a single search of the same references is needed for all the claims, as in this case. For these reasons, Applicants believe that claims 69-72 (Group II) should be considered along with claims 1-68 and 72-81 (Group I). Applicants respectfully solicit reconsideration and withdrawal of the restriction requirement.

The Examiner has required election of a species of Formula II; Applicants request that rejoinder of claims not drawn to this species be considered at the appropriate time.

The additional election requirements do not appear to lessen the Examiner's burden, and the reasons for these are not clear. None of these elections further reduce the number of claims that the Examiner needs to consider nor the amount of art that the Examiner needs to search. Applicants respectfully solicit reconsideration and withdrawal of these election requirements.

Applicants believe that claims 1-81 are patentable and solicit allowance thereof at an early date.

No fee is believed to be due herewith, but should any fee be due it may be charged to Dep. Acct. #01-1425.



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